

### **REMARKS**

Reconsideration of the rejections set forth in the Office Action dated September 12, 2003 is respectfully requested. Applicants petition the Commissioner for a 1-month extension of time. A separate petition accompanies this amendment.

#### **I. Amendments**

The specification is amended in accord with M.P.E.P. § 201.11 III(G) to delete a benefit claim to U.S. Patent No. 5,013,556.

Claims 8 and 13 are amended to remove the hydrophilic polymer polyethylene glycol from the Markush group.

#### **II. Board's Decision and Entitlement to Priority**

##### **A. Decision of the Board of Patent Appeals and Interferences**

In the decision dated December 21, 2003 from the Board of Patent Appeals and Interferences (BPAI) two points are raised that Applicants addresses here.

First, on page 6 of the decision, the Board asks the Examiner to "clarify whether the references cited by Appellants have in fact been submitted" (page 6, lines 4-7). Applicants direct the Examiner to the response submitted October 21, 1999 which included copies of the cited references. If for some reason these documents are missing from the USPTO file, Applicant can provide another copy.

Second, the Board asks the Examiner to determine, on the record, whether or not the instant claims are entitled to the effective filing date of the '556 patent under 35 U.S.C. § 120 (page 9, last paragraph). In the Office action dated September 19, 2003, the Examiner puts forth "new rejections based on the fact that applicants are not entitled to priority of the 07/425,224 (as also noted by the board as described on pages 8 and 9 of the remand)" (Office action, September 19, 2003, page 2, first paragraph).

On pages 8 and 9 of the Board's decision, the Board states that the present claims "appear" to be unsupported by the '556 patent, and emphasize that they are "not finding as a matter of fact that the '556 patent does not adequately describe the instant claims."

By raising this issue, Applicants only wish to clarify the finding of the Board and that the Examiner was charged with determining on the record whether or not the claims are entitled to priority.

B. Amendment of Priority Claim

By this amendment, and as discussed above, applicants hereby delete the prior claim to priority of U.S. Patent No. 5,013,556.

III. Withdrawal of Previously Recorded Terminal Disclaimer

In accord with M.P.E.P. § 1490 applicants submit herewith a petition under 37 C.F.R. § 1.182 requesting withdrawal of the terminal disclaimer filed on October 21, 1999. In this 1999 Terminal Disclaimer, extension of the patent term over U.S. Patent Nos. 5,013,556 and 5,213,804 was disclaimed. In light of the present to the instant claims, and the amendment to remove any priority claim, applicant seeks withdrawal of the terminal disclaimer over 5,013,556. Thus, withdrawal of the previously submitted terminal disclaimer is requested in favor of a presently submitted disclaimer over only the 5,213,804 patent.

IV. Rejection Under 35 U.S.C. §102(e)

Claims 8, 9, and 12-19 were rejected under 35 U.S.C. §102(e) as anticipated by Woodle *et al.* (U.S. Patent No. 5,013,556).

This rejection is respectfully traversed.

A. The Present Invention

The invention as set forth in the present claims is directed to a liposome composition for treating a systemic infection which is localized at a site other than the fixed macrophages residing in the liver or the spleen. The composition includes;

- (i) liposomes composed of vesicle forming lipids, and including an amphipathic vesicle-forming lipid derivatized with polyglycolic acid, polylactic acid, a copolymer of polyglycolic acid and polylactic acid, and polyvinyl alcohol; the liposomes having an extended blood circulation lifetime;

- (ii) a therapeutic agent entrapped in the liposomes; and
- (iii) an ability to accumulate in the infected tissue following intravenous administration.

B. The Cited Document

WOODLE ET AL. relate to liposomes having an external coating of a polyalkylether polymer, as exemplified by polyethyleneglycol.

C. Analysis

The standard for lack of novelty, that is, for anticipation, is one of strict identity. To anticipate a claim for a patent, a single prior source must contain all its essential elements. M.P.E.P. § 2131.

As noted above an element of the present claims is liposomes that include including an amphipathic vesicle-forming lipid derivatized with polyglycolic acid, polylactic acid, a copolymer of polyglycolic acid and polylactic acid, and polyvinyl alcohol. Woodle *et al.* nowhere describes liposomes derivatized with one of these polymers.

Thus, the standard of strict identity has not been met, and withdrawal of the rejection under 35 U.S.C. § 102 is respectfully requested.

V. Rejection Under 35 U.S.C. §103

Claims 8, 9, and 11-19 were rejected under 35 U.S.C. §103 as allegedly obvious over Woodle *et al.* (U.S. Patent No. 5,013,556).

This rejection is respectfully traversed.

A. Summary of the Present Invention

A summary of the present claims is given above.

B. Summary of the Cited References

A summary of the cited Woodle *et al.* reference is given above,

**C. Analysis**

According to the MPEP § 2143, "to establish a prima facie case of obviousness, .... the prior art references (or references when combined) must teach or suggest all the claim limitations."

The present claims are directed to liposomes that include including an amphipathic vesicle-forming lipid derivatized with polyglycolic acid, polylactic acid, a copolymer of polyglycolic acid and polylactic acid, and polyvinyl alcohol. Woodle *et al.* nowhere describes liposomes derivatized with one of these polymers.

Thus, the required standard that the cited references must teach or suggest all the claim limitations has not been met, and withdrawal of the rejection under 35 U.S.C. § 103 is respectfully requested.

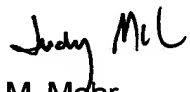
**VI. Conclusion**

In view of the above remarks, Applicants submit that the claims now pending are in condition for allowance. A Notice of Allowance is, therefore, respectfully requested.

The Examiner is invited to contact Applicants' representative at the number below as needed to further prosecution of this application.

Respectfully submitted,

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